

A-1789

We claim:

1. A method for detecting ITA in a biological sample comprising the step of:
contacting a biological sample obtained from a subject with antibodies that bind ITA,
in one assay,
wherein the assay comprises at least two capture antibodies that specifically bind
different epitopes of ITA, and at least one detection antibody that binds an epitope
of the ITA distinct from the capture antibody epitopes, and
wherein the detection antibody is coupled to a label that produces a detectable
signal, wherein the presence of the detectable signal indicates the presence of ITA
in the biological sample.
2. The method of claim 1, wherein the assay is a chemiluminescent sandwich assay.
3. The method of claim 1, wherein the chemiluminescent assay is automated.
4. The method of claim 1, wherein the biological sample is a liquid sample.
5. The method of claim 4, wherein the biological sample is a urine sample.
6. The method of claim 4, wherein the biological sample is a serum sample.
7. The method of claim 1, wherein the biological sample is a tissue sample.
8. The method of claim 1, wherein one capture antibody is raised against ITA.
9. The method of claim 8, wherein the capture antibody is designated B152.
10. The method of claim 1, wherein one capture antibody is raised against hCG or a
fragment thereof.

A-1789

11. The method of claim 10, wherein the capture antibody is designated clone 820.
12. The method of claim 10, wherein the capture antibody is designated clone 827.
13. The method of claim 1, wherein one capture antibody is designated B152, and the other capture antibody is designated clone 820.
14. The method of claim 1, wherein the detection antibody is raised against the beta subunit of hCG.
15. The method of claim 14, wherein the detection antibody is designated B207.
16. The method of claim 1, wherein the detection of ITA in the biological sample indicates the presence of a trophoblastic disease in the subject.
17. The method of claim 1, wherein the detection of ITA in the biological sample indicates the presence of a choriocarcinoma in the subject.
18. The method of claim 1, wherein the detection of ITA in the biological sample indicates the presence of a hydatidiform mole in the subject.
19. In a chemiluminescent immunoassay, a method for detecting ITA in a biological sample comprising the steps of:
 - a) contacting the biological sample with a monoclonal capture antibody designated B152; and
 - 5 b) contacting the biological sample with a monoclonal detection antibody designated B207,
wherein the capture and detection antibodies bind different epitopes of ITA, and
wherein the detection antibody is coupled to a label that produces a
10 detectable chemiluminescent signal,

thereby detecting ITA in the sample.

20. The method of claim 19, further comprising contacting the biological sample with an additional monoclonal capture antibody designated clone 820.
21. The method of claim 19, wherein the detectable signal is produced by an acridinium label.
22. The method of claim 19, wherein the steps are automated.
23. A method for detecting a trophoblastic disease in a subject comprising the steps of:
 - a) contacting a biological sample from the subject with antibodies that specifically bind ITA and hCG , in one assay;
 - b) confirming that the subject is not pregnant; and
 - 5 c) comparing the amounts of ITA and hCG in the sample to standard ITA and hCG amounts obtained from a population of normal subjects, wherein a higher amount of ITA and hCG in the sample as compared to the standards indicates the presence of a trophoblastic disease.
24. The method of claim 23, wherein the trophoblastic disease is a choriocarcinoma.
25. The method of claim 23, wherein the trophoblastic disease is a hydatidiform mole.
26. A diagnostic kit comprising
 - a) a capture antibody solution, wherein the capture antibody solution comprises a plurality of capture antibodies that specifically bind to different epitopes of ITA; and
 - 5 b) a detection antibody solution, wherein the detection antibody solution comprises an antibody that binds ITA and is coupled to a label.

A-1789

27. The diagnostic kit of claim 26, wherein one monoclonal capture antibody is designated B152.
28. The diagnostic kit of claim 26, wherein one monoclonal capture antibody is designated clone 820.
29. The diagnostic kit of claim 26, wherein one monoclonal capture antibody is designated clone 827.
30. The diagnostic kit of claim 26, wherein one monoclonal capture antibody is designated B152 and another monoclonal capture antibody is designated clone 820.
31. The diagnostic kit of claim 26, wherein one monoclonal capture antibody is designated B152 and another monoclonal capture antibody is designated clone 827.
32. The diagnostic kit of claim 26, wherein the detection antibody binds the beta subunit of ITA.
33. The diagnostic kit of claim 32, wherein the detection antibody is designated B207.
34. The diagnostic kit of claim 26, wherein the label is a colored particle.
35. A diagnostic kit comprising
 - a) a plurality of reagent containers;
 - b) a capture antibody solution in one container, wherein the capture antibody solution comprises at least one antibody that specifically binds ITA; and
 - c) a detection antibody solution in one container, wherein the detection antibody solution comprises an antibody that binds ITA and is coupled to a chemiluminescent label.

A-1789

36. The diagnostic kit of claim 35, wherein the capture antibody solution comprises two antibodies that specifically bind different epitopes of the ITA.
37. The diagnostic kit of claim 36, wherein the capture antibodies are designated B152 and clone 820.
38. The diagnostic kit of claim 36, wherein the capture antibodies are designated B152 and clone 827.
39. The diagnostic kit of claim 35, wherein the detection antibody binds the beta subunit of ITA.
40. The diagnostic kit of claim 39, wherein the detection antibody is designated B207.
41. The diagnostic kit of claim 35, further comprising a luminometer to measure a signal produced by the chemiluminescent label.